IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No.	:	10/630,883
Applicant	:	Foerster et al.
Filed	:	07/30/2003
Group Art Unit:		3736
Examiner	:	Szmal
Docket No.	:	END-897DIV2
Customer No.:		021884
Title	:	METHODS AND DEVICES FOR DEFINING AND MARKING TISSUE

APPEAL BRIEF

Mail Stop Appeal Brief - Patents
Commissioner of Patents and Trademarks
PO Box 1450
Alexandria, VA 22313-1450

Sir:

REAL PARTY IN INTEREST

Ethicon Endo-Surgery, Inc. is the real party in interest in the above referenced patent application.

RELATED APPEALS AND INTERFERENCES

Neither Appellants' representative, Appellants' assignee, nor Appellants are aware of any appeals and/or interferences effected by or having a bearing on the Board's decision in the pending appeal. However, it is noted that the original claims in this case were copied from issued U.S. Patent No. 6,427,081.

STATUS OF CLAIMS

Claims 46-51 are currently pending and stand finally rejected. Claims 1-45 have been canceled. Accordingly, Appellants appeal the Examiner's Final Rejection of claims 46-51.

STATUS OF AMENDMENTS

An amendment after final rejection is being filed herewith. This amendment after final rejection addresses an informality noted in the Office Action of June 19, 2008. The amendment is neither believed to raise new issues nor require undue consideration as it merely corrects a typographical error in a manner suggested by the Examiner. Accordingly this amendment should be entered and Appellants have included these amendments in the Claims Appendix.

As to the amendments filed prior to the final rejection, all amendments appear to have been entered and considered.

SUMMARY OF THE CLAIMED SUBJECT MATTER

Claims 46 and 51 are the only independent claims involved in the present Appeal. As such, claims 46 and 51 are summarized below. In addition dependent claim 50 is argued separately and, therefore, is summarized below.

Claim 46 defines an intracorporeal marker marking a cavity site within the body of a mammalian patient from which a tissue sample has been removed during a biopsy. The intracorporeal marker includes a mass of material that is detectable by at least two remote imaging detection methods when introduced into the cavity site created when the tissue has been removed. The mass of material remains detectable at the cavity site for a first period of time after the mass is introduced into the cavity site. The mass of material does not interfere with imaging of tissue adjacent the cavity site after the first period of time. Specification, Page 23, lines 4-6, Page 3, lines 12-16 and Page 15, lines 6-9.

Claim 51 defines a marker marking a cavity site from which a tissue sample has been removed during a biopsy. The marker includes a mass of material that is detectable by at least two remote imaging detection methods when introduced into the cavity site created when the tissue has been removed. The mass of material remains detectable for a first period of time after the mass is introduced into the cavity site. The mass of material does not interfere with imaging of tissue adjacent the cavity site after the first period of time. Specification, Page 23, lines 4-6, Page 3, lines 12-16 and Page 15, lines 6-9.

Claim 50 depends from claim 46 and further defines that the detectable mass will interfere with imaging of tissue adjacent to the cavity site and will remain at the site in sufficient quantity to permit location of the cavity site by imaging through the first period of time and will then clear

sufficiently from the site so as to not interfere with imaging of tissue adjacent to the cavity site. Specification, Page 23, lines 4-6.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. Whether claims 46-51 is unpatentable under 35 U.S.C. § 102(b), as being anticipated by U.S. Patent No. 4,832,686 to Anderson ("Anderson").

ARGUMENTS

I. CLAIMS 46-51 ARE PATENTABLE OVER ANDERSON.

Claims 46-51 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Anderson. As discussed above, independent claims 46 and 51 both define a marker for marking a cavity site. In particular, claim 46 defines an intracorporeal marker for marking a cavity site within the body of a mammalian patient from which a tissue sample has been removed during a biopsy. The intracorporeal marker includes a mass of material that is detectable by at least two remote imaging detection methods when introduced into the cavity site created when the tissue has been removed. The mass of material remains detectable at the cavity site for a first period of time after the mass is introduced into the cavity site. The mass of material does not interfere with imaging of tissue adjacent the cavity site after the first period of time.

The patent laws require that each and every element of a claimed invention be found in the prior art before that claim will be anticipated under 35 U.S.C. § 102(b). The outstanding rejection fails to show that Anderson discloses each element of the claimed invention and the rejection is, therefore, considered to be improper.

In contrast to the arguments presented by the Examiner, Anderson fails to disclose each of the elements defined in claims 46, 50 and 51. Anderson does not disclose a detectable mass of material that remains detectable at the cavity site for a first period of time after introduction into the cavity and does not interfere with the imaging of the tissue adjacent the cavity site after the first period of time.

While Anderson does discuss the utilization of radiopaque markers in conjunction with a bioerodable, biocompatible polymer, Anderson is totally silent as to the manner in which the sample would be detectable and the periods of time during which the material would be detectable. In fact,

there is no indication the radiopaque markers of Anderson are bioerodable and do not interfere with imaging after the first period of time or, as set forth in claim 50, interfere with the tissue adjacent the cavity site and remain at the site in sufficient quantity to permit location of the cavity site by imaging. The Office Action presumes that "the ability of the material to degrade in a specified period of time would also inherently disclose the ability to image the site for a first predetermined period of time and not interfere with imaging during a second period of time". Unfortunately, this statement by the Examiner is unsupported by the technology disclosed by Anderson. In particular, although it is certainly possible that a bioerodable composition could degrade during a first period of time, there is no disclosure in Anderson that the imaging component thereof is also bioerodable. The radiopaque marker of Anderson might remain at the treatment site for a period greater than the claimed first period of time, or even permanently and there is no telling based upon the disclosure of Anderson.

Quite frankly, Anderson is silent with regard to when and how the radiopaque markers disclosed are to be imaged. Thus, the Examiner has just set forth his "assumptions" and in no way has shown that Anderson "inherently" discloses the claimed elements. If something is inherent in a prior art reference, it definitively belongs to or is part of the prior art reference. That is, the feature is instrinsically part of the prior art reference. What the Examiner has done is made assumptions regarding Anderson so as to create a rejection. These assumptions are not inherent to Anderson. A § 102 rejection is deemed improper if based upon assumptions, and not what the reference actually teaches. In fact, the Examiner's entire rejection is based upon unsupported assumptions regarding Anderson, as all Anderson discloses is the following:

> In addition to IL-2 and the bioerodible polymer, other materials may also be incorporated into the composition, specifically: other immunotherapeutic agents, such as B-cell growth factor, alpha interferon, gamma interferon, interleukin-1, and the like; therapeutically effective amounts of chemotherapeutic agents such as

> antiproliferative agents and cytotoxic agents, including cytosine arabinoside, the nitrosoureas (BCNU or methyl-CCNU), procarbazine, streptozotocin, vincristine, and the like; antibiotics; hemostatic agents, such as thrombin; radiopaque markers; and stabilizers for IL-2, such as polyethlyene glycol and albumin; all in effective or therapeutic amounts.

From that, the Examiner assumes that the radiopaque markers are transformed into a radiopaque substance uniformly dispensed in the composition of Anderson to form a bioabsorbable marker. While it is possible to provide for a radiopaque substance to uniformly disperse, it is not inherently part of Anderson's disclosure as the radiopaque marker of Anderson may act and function in a wide variety of manners know to those skilled in the art. Regardless of whether the assumption is possible, it is merely an assumption and the assumption is not inherent in or supported by the disclosure of Anderson.

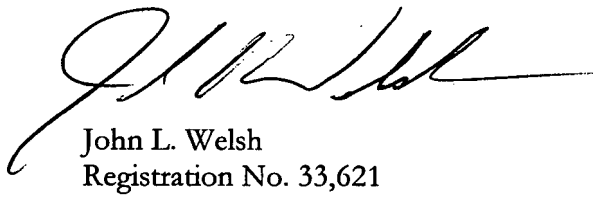
With the foregoing in mind, the Examiner's assumption that the composition disclosed by Anderson would function as claimed in accordance with the present invention is unsupported and is not inherent of the radiopaque markers disclosed by Anderson. The rejection based thereon is, therefore, believed to be improper as Anderson does not disclose each and every feature of the claimed invention.

With this in mind, it is Appellants' opinion the rejection of independent claims 46 and 51, as well as dependent claim 50, under 35 U.S.C. § 102 is improper and Appellants respectfully request the rejections be withdrawn. As to the rejection of claims 47, 48 and 49, these claims are dependent upon independent claims 46 and Appellants believe these claims overcome Anderson for at least the reasons presented above. As such, Appellants respectfully request the rejection of these claims also be withdrawn.

II. CONCLUSION

In conclusion, Appellants have now shown that the § 102 rejection is improper and the reference cited by the Examiner neither disclose nor suggest the claimed invention. Therefore, it is respectfully requested that the outstanding rejections of claims 46-51 be reversed.

Respectfully submitted,



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CLAIMS APPENDIX
(Assuming the After Final Amendment is entered)

1-45. (Cancelled)

46. An intracorporeal marker marking a cavity site within the body of a mammalian patient from which a tissue sample has been removed during a biopsy, comprising a mass of material that is detectable by at least two remote imaging detection methods when introduced into the cavity site created when the tissue has been removed, that remains detectable at the cavity site for a first period of time after the mass is introduced into the cavity site and that does not interfere with imaging of tissue adjacent the cavity site after the first period of time.

47. The marker of Claim 46 wherein the detectable mass is imageable, and remains imageable for the first period of time, but then clears sufficiently from the cavity site so as to not interfere with imaging of tissue adjacent the site during the second predetermined time period.

48. The marker of Claim 47 wherein the detectable mass is imageable by at least one of methods consisting of:

fluoroscopy;

X-ray;

Mammography;

Magnetic resonance imaging;

Ultrasound.

49. The marker of Claim 46 wherein the detectable mass is detectable by at least two remote imaging detection methods selected from the group consisting of:

Magnetic resonance imaging (MRI);

Ultrasound imaging;

x-ray imaging;

mammography;

fluoroscopy.

50. The marker of Claim 46 wherein the detectable mass will interfere with imaging of tissue adjacent to the cavity site and will remain at the site in sufficient quantity to permit location of the cavity site by imaging through the first period of time and will then clear sufficiently from the site so as to not interfere with imaging of tissue adjacent to the cavity site.

51. A marker marking a cavity site from which a tissue sample has been removed during a biopsy, the marker comprising a mass of material that is detectable by at least two remote imaging detection methods when introduced into the cavity site created when the tissue has been removed, that remains detectable for a first period of time after the mass is introduced into the cavity site, and that does not interfere with imaging of tissue adjacent the cavity site after the first period of time.

EVIDENCE APPENDIX

Not Applicable

RELATED PROCEEDINGS APPENDIX

Not Applicable